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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/601,019 10/17/00 ROMBI

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EXAMINER

PATTEN, P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED:

11/02/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/601,019

Applicant(s)

Rombi, M.

Examiner

Patricia Patten

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Aug 23, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1 and 3-21 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1 and 3-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

✓

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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DETAILED ACTION

Claims 1 and 3-21 are pending in the application and were presented for examination on the merits.

Applicant's arguments presented 8/23/01 are moot in light of the new rejections which follow.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph. Claim 1 is confusing in that it is not clear whether the extract contains 20-30% of the catechols, or whether the composition as a whole contains 20-30% of the catechols. Correction is necessary.

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Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 6 recites a method for manufacturing, however, merely cites a method for obtaining an extract, thus, it appears that the method is incomplete. Clarification is needed.

Claims 11-15, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-15 recite ‘a method for the esthetic treatment of a human being...’. The term ‘esthetic,’ which is rendered vague, is not clearly defined in the specification. The term is defined varies with regard to culture and location. It is suggested that the claim read ‘a method for promoting weight loss’ or a ‘method for treating obesity’ in order to avoid confusion.

Claims 11-15 are further indefinite in that these claims either recite ‘catechol-enriched’ or are dependant upon a claim which recites ‘catechol-enriched.’ This term is vague and indefinite in that it is unclear what ‘enriched’ is referring to. Are additional catechols introduced into a green tea extract, or is the extract deemed to be ‘enriched.’ The term itself is vague in that the parameters are not clear. What is the term ‘enriched’ being compared to? Correction is necessary.

Claim 4 recites ‘the concentration of caffeine.’ This statement lacks antecedent basis in claim 1, because claim 1 does not recite the term ‘caffeine.’ A suggestion to overcome the

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rejection would be to rephrase the claim to read: ‘ wherein the extract contains caffeine, and wherein the ratio of the concentration of catechols to caffeine in the extract is...’.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al. (US 5,776,756). Claims 1, 3-10 and 16-18 are drawn to a composition comprising an extract of green tea containing from 20-30% by mass of catechols expressed as epigallocatechol gallate (EGCG). Claims are further drawn to where the extract of green tea contains from 5-10% by mass of caffeine, wherein the ratio of the concentration of catechols to caffeine is between 2 and 10, wherein the extract of green tea is titrated to allow daily administration. Claims 6-10 are further drawn to a method of manufacturing the medicament. Claims 11-16 are drawn to a method for the esthetic treatment of a human being, wherein said method comprises the oral administration of a catechol-enriched extract of green tea.

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Green tea extracts were well known in the art. For example, Kimura et al. (US 5,776,756) disclosed that extracts of green tea could have been produced via extraction with ethanol, methanol, or mixtures of ethanol and water (col.4, lines 33-47). Although Kimura et al. did not specifically disclose extraction via an 80% ethanol solution, the Examiner cannot find a significant difference between the extracted product disclosed by Kimura et al. and the product as Instantly claimed. "...or a mixture of ethanol and water": it is thought that any mixture of ethanol and water would produce similar constituents, although in varying proportions; i.e., if A and B were present in the raw plant material (consider A is epigallocatechol gallate and B is caffeine), and a 50% ethanol solution were used to extract (assuming a 50% water concentration), a yield may be 2mg of A and 1mg of B for example. If, instead, the extract were performed with a 70% ethanol extraction, the yield may be in the order of 3mg A and 2mg of B (approximated). Although the percentages of the constituents would have increased due to the increased percentage of ethanol and water, the constituents would have remained the same (A and B). Thus, is the claimed composition different with respect to the prior art reference which already taught ethanol or ethanol/water extracts? The MPEP states that:

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are

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not." *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

It is deemed in the instant case that the product obtained from a 100% ethanol extract from green tea or an 80% ethanol extract from green tea would be so similar that no discernable difference could be detected with regard to functionality of the composition, especially lacking substantial evidence to the contrary. One of ordinary skill in the art would have been motivated to have adjusted the ratios of ethanol to water in order to produce varying levels of active ingredients. Adjustments of active ingredients in a pharmaceutical composition was merely considered routine optimization of a result effective variable. Thus, it would have been well within the purview of the ordinary artisan at the time the invention was made to have increased or decreased the amounts of active ingredients in the green tea extract especially in the present case where the extract (water, ethanol or ethanol/water) was known to be pharmaceutically effective as clearly taught by Kimura et al.

Claims 11-15 and 19-20 state a method for the esthetic treatment of a human being, wherein the method is simply administration of green tea extract. Kimura et al. taught administration of the green tea extract to humans (Please see Examples). Thus, one of ordinary skill in the art would have been motivated to have administered the composition disclosed by Kimura et al. because it was shown to have displayed pharmaceutical properties. Wherein the claims state 'in order to bring about a loss of weight' is considered an intrinsic property of the

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method which must have taken place since the method steps were the same, although the reference did not explicitly teach where the extract was beneficial for weight loss.

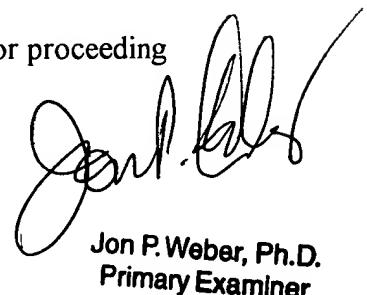
From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner